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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,422	01/16/2004	Leif Andersson	62781.000013	5639

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EXAMINER

WOOLWINE, SAMUEL C

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/758,422	Applicant(s) ANDERSSON ET AL.	
	Examiner Samuel Woolwine	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,6-10,34,35 and 42 is/are pending in the application.
- 4a) Of the above claim(s) 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10,34 and 35 is/are rejected.
- 7) ☒ Claim(s) 8,9 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/12/2005</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an applications filed in the United Kingdom on 05/30/97 and 01/31/98. It is noted, however, that applicant has not filed a certified copies of the 9711214.8 and 9801990 applications as required by 35 U.S.C. 119(b).

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-3, 6-10 and 34-35, in the response filed 06/14/2006 is acknowledged. Applicant traverses on the assertion that the requirement for restriction is improper in that a search for both groups would not constitute a burden. This argument is not persuasive. Notwithstanding the amendment to the claim, claim 42 is still so broad as to encompass a nearly unlimited number of items (note consisting essentially of *one or more reagents* would read on, for example, dNTPs, which term is found in 24,973 documents in the US Patent database at the time of this writing). The requirement for restriction is still deemed proper and made FINAL. As such, claim 42 is withdrawn from further consideration.

### ***Claim Objections***

Claims 8 and 9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim (in this case, claim 6). See MPEP § 608.01(n). Accordingly, the claims 8 and 9 have not been further treated on the merits.

A further objection to claim 34 is noted, in that claim 34 is dependent on any one of claims 7, 10, 11, 14-23 and 28-33. However, as claims 11, 14-23 and 28-33 have been cancelled, claim 34 should be amended to omit reference to these cancelled claims.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 7, 34 and 35, the phrase "for example" (in claims 7 and 34) renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). For purposes of further examination, it will be assumed these "for example" limitations are not part of the claimed invention. It is also unclear what "validating an animal product" means.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph-Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, 7, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to:

- 1) differentiating animals and animal products on the basis of breed origin; or
- 2) determining or testing the breed origin of an animal product; or
- 3) validating an animal product;

comprising the steps of:

- (i) providing a sample from any animal product, and
- (ii) analyzing any allele(s) of any one or more breed determinant genes present

in the sample.

These claims encompass an extremely large genus of (undisclosed) alleles correlated to any phenotype from any animal. These phenotypes include, but are not limited to, the numerous examples recited in claim 6, such as coat texture, coat density, coat length, ear aspect, horn morphology, tusk morphology, eye color, plumage, beak color, vocalization, comb or wattle (morphology? color? size?), and display behavior. The specification does not disclose ANY of these phenotypes as being related to any particular gene or allele, nor does the art of record even indicate whether this is known in the art today, much less as of the date of filing.

The specification has only taught specific alleles (i.e. polymorphisms) in the porcine *aMSHR* and *KIT* genes. These specific polymorphisms are not a representative

sample of all polymorphisms in all animals, most of which have yet to be discovered, but which are nonetheless encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed (See Vas-Cath at page 1117).” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (See Vas-Cath at page 1116).”

The skilled artisan cannot envision the detailed chemical structure of the encompassed alleles, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that ‘the inventor invented the claimed invention.’ Lockwood v. American Airlines, Inc.,

Art Unit: 1637

107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ('[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'). Thus, an applicant complies with the written description requirement 'by describing the invention, with all its claimed limitations, not that which makes it obvious,' and by using 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.' Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, 'an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.' Id. at 1170, 25 USPQ2d at 1606."

Accordingly, absent a teaching of a representative number of alleles of a representative number of genes from a representative number of animals such that one of ordinary skill in the art could envision the entire, literally infinite genus thereof, the specification provides insufficient written description to support the broadly claimed genus.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 7 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Joerg et al (cited reference 8 on the IDS of 8/12/2005).

With regard to claim 1, Joerg teaches a method comprising:

*(i) providing a sample of the animal product (bovine genomic DNA; see page 317, column 1, lines 11-13 of 2<sup>nd</sup> paragraph);*

*and (ii) analyzing the allele(s) of one or more breed determinant genes present in the sample (alleles of MSHR, which affects coat color, and thus qualifies as a breed determinant gene).*

Joerg teaches analysis of the alleles of *MSHR* by both sequencing (see figure 1, for example) as well as by RFLP (see page 317, column 2, last 8 lines carrying over to page 318).

With regard to claim 3, coat color is a polygenic trait, as evidenced by what Joerg states in the first sentence of the article ("...controlled primarily by two loci..."). This is also attested to by Applicant on line 32, page 9 of the specification.

With regard to claim 6, Joerg teaches a coat color gene (see entire document, for example the title).



With regard to claim 7, Joerg teaches the *MSHR* gene. While Joerg does not refer to it as  $\alpha$ *MSHR*, one of ordinary skill in the art would clearly understand this is the same gene to which Applicant refers, since Joerg teaches this is the melanocyte-stimulating hormone receptor (compare Joerg page 317, column 1, lines 10-11 with page 11, lines 23-24 of the specification).

With regard to claim 34, Joerg teaches RFLP (see page 317, column 2, last 8 lines carrying over to page 318).

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by McPherron et al (1997).

With regard to claim 1, McPherron teaches a method comprising:

*(i) providing a sample of the animal product (DNA);*

*and (ii) analyzing the allele(s) of one or more breed determinant genes present in the sample* (see page 84, column 2, last complete sentence; see also figure 3).

McPherron teaches a method of analyzing alleles (wild type vs. null) of GDF-8. The null allele results in a double-muscled phenotype (see last paragraph on page 84, continuing on page 87, and see first full paragraph on page 87).

With regard to claim 2, since McPherron himself created the null allele in the mice, it is clear that the double-muscled phenotype is a monogenic trait.

With regard to claim 6, McPherron teaches the double-muscled phenotype.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Joerg et al (cited reference 8 on the IDS of 8/12/2005) in view of Andersson et al (WO 97/05278, cited on the IDS of 8/12/2005).

Joerg teaches a method comprising obtaining a sample of bovine nucleic acid (bovine genomic DNA; see page 317, column 1, lines 11-13 of 2<sup>nd</sup> paragraph), and analyzing the nucleic acid to determine which allele or alleles of the *aMSHR* gene is/are present (see figure 1, and see page 317, column 2, last 8 lines carrying over to page 318). Joerg also teaches the *aMSHR* gene is present in humans, horses, and mice (see page 317, column 1, lines 7-13 of 1<sup>st</sup> paragraph and lines 6-9 of 2<sup>nd</sup> paragraph). Joerg also teaches the *MSHR* locus contributes to coat color in mice, horses and cattle (ibid). Joerg does not teach analyzing pig DNA.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the method taught by Joerg for cloning and sequencing alleles of the bovine *MSHR* gene to pigs by cloning and sequencing alleles of the *MSHR* gene from pigs. In doing so, one would have performed the method of claim 10. One would have been motivated to do so because Andersson teaches:

"Coat colour is important to the pig breeding industry for a number of reasons. Firstly, in a number of markets there is a preference for white skinned meat. This is due to the fact that pork is often marketed with the skin still attached, and skins from coloured pigs, even if dehaired, can still exhibit coloured hair roots, which can lead to a negative perception by the consumer, since the surface of the meat may appear to be

Art Unit: 1637

spotted by mould. It is necessary, therefore, in these markets, to remove the skin from such carcasses, entailing additional cost. For example, in the US, coloured carcasses are associated with approximately 1% of skin defects requiring dehairing and skinning to remove pigment. As a result of this, coloured pig carcasses are generally discounted.”

### ***Conclusion***

No claims are allowed.

Claim 35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

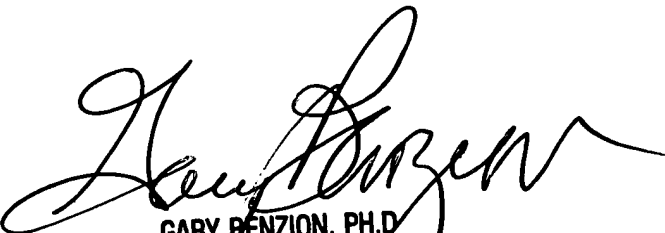
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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